

REMARKS

Claims 6, 7 and 9 were pending in the present application. Claims 6, 7 and 9 are cancelled without prejudice and new claims 21-32 are added. Support for new claims 21, 22 and 23 can be found, *inter alia*, in the original claims 1 and 6, on page 7, lines 17-21 of the original specification. Support for new claims 24-27 can be found, *inter alia*, in the original claims 1, 6 and 7. Support for new claims 28 and 29 can be found, *inter alia*, in the original claims 8 and 9. Support for new claim 30 can be found, *inter alia*, in the original claim 3. Support for new claim 31 can be found, *inter alia*, in the original claim 5. Support for new claims 32 can be found, *inter alia*, in the original claim 11. Applicants submit that new claims 21-32 are fully supported by the original specification and do not raise any issue of new matter. Therefore, entry of the present Amendment, including new claims 21-32, is respectfully requested. Upon entry of the present Amendment, claims 21-32 will be under examination.

REJECTION OF CLAIMS UNDER 35 U.S.C. §102(b)

Claims 6 and 7 stand rejected under 35 U.S.C. §102(b) for allegedly being anticipated by Miller, U.S. Patent No. 5,728,719 (hereinafter "Miller").

This rejection is moot with respect to claims 6 and 7 because these claims are cancelled. Moreover, even if Miller is applied to new claims 21-32, it does not anticipate these new claims as Miller does not disclose any solid implant which is stable for up to 30 weeks at 30⁰C at an electron irradiation level of up to 25 kGy. Accordingly, reconsideration and withdrawal of Miller as an anticipating reference are respectfully requested.

CLAIM REJECTION UNDER 35 U.S.C. §103(a)

Claims 6, 7 and 9 stand rejected under 35 U.S.C. §103(a) over Roorda et al., U.S. Patent No. 5,543,156 (hereinafter "Roorda") in view of Miller.

This rejection is also moot with the cancellation of claims 6, 7 and 9. Applicants further contend that new claims 21-32 are nonobvious over the combination of Roorda and Miller for the following reasons:

The combination of Roorda and Miller does not teach or suggest each and every element of new claims 21-32 as required by M.P.E.P. § 2142 to establish a *prime facie* case of obviousness. In particular, the Roorda-Miller combination does not teach or suggest any solid implant which is stable for up to 30 weeks at 30⁰C at an electron

irradiation level of up to 25 kGy.

Moreover, without looking at the disclosure of the present application, one of ordinary skill in the art would not know from Roorda-Miller combination how to obtain the claimed solid implant which is stable for up to 30 weeks at 30°C at an electron irradiation level of up to 25 kGy. Furthermore, applicants have achieved unexpected results, i.e., the claimed solid implant remains stable for an extended period of time under intense electron irradiation.

In addition, Roorda requires that use of an “erodible delivery devices” which “comprise (a) a body formed of a bioerodible polymer or polymers together with a required excipient not generally considered to be a pore-former and (b) an active ingredient.” (see abstract of Roorda). Miller disclosed “method of preventing infection and disease caused by endoparasites ... is the combination in a single product of a systemically active nitrogen containing heterocyclic compound of the invention as defined above and one of the compounds of the antibiotic class effective against endoparasites...” (see Col. 5, Lines 43-60 of Miller). Applicants respectfully point out that new claims 21-32 of the present application do not include “a body formed of a bioerodible polymer or polymers together with a required excipient not generally considered to be a pore-former” of Roorda. Nor do these new claims include “a systemically active nitrogen containing heterocyclic compound” of Miller. Applicants submit that even assuming that the composition from Roorda-Miller combination also achieved stability for an extended period of time under electron irradiation, new claims 21-32 would still be nonobvious over these references because “the omission of an element and retention of its function is an indicia of unobviousness.” *see M.P.E.P. §2144.04(II)(B)*. Accordingly, reconsideration and withdrawal of Roorda and Miller as §103 references are respectfully requested.

CONCLUSION

In view of the present Amendment and remarks, Applicants believe that the new claims are allowable and respectfully request the issuance of a Notice of Allowance with regard to all pending claims. The Examiner is also encouraged to contact the undersigned if he has any questions.

Respectfully submitted,

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